

EXHIBIT 3



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Re: Response to December 16, 2022, Request for Additional Information

Dear Mr. Siclari:

This firm represents Ascent Pharmaceuticals, Inc. ("Ascent"). We write in response to your office's December 16, 2022, Request for Additional Information.

Comment No. 1, concerning Ascent Attachment 1:

Several extracted pages of Batch Packaging Records (BPRs) provided in Ascent Attachment 1 relate to lot numbers for which Ascent did not previously provide either Batch Manufacturing Records (BMRs) or BPRs. Other extracted pages conflict with BPRs previously provided DEA. Kindly provide a complete set of BMRs and BPRs that relate to all lot numbers of methylphenidate 20 mg listed in Ascent Attachment 1.

Response to Comment No. 1:

Today Ascent has sent to your office a USB drive that contains a complete set of BMRs and BPRs for Methylphenidate 20 mg Tablets ([Attachment-1](#)) that it shipped in 2021 and 2022. And below is a table-1 that reflects the lot numbers and shipment dates for those tablets.

TABLE-1

Product Name	Lot #	Strength (mg)	Date Shipped
Methylphenidate HCL Tablets	20111138	20	2/15/2021
Methylphenidate HCL Tablets	20111139	20	2/23/2021
Methylphenidate HCL Tablets	20111140	20	3/1/2021
Methylphenidate HCL Tablets	21030200	20	3/31/2021
Methylphenidate HCL Tablets	21030201	20	4/14/2021
Methylphenidate HCL Tablets	21030202	20	4/14/2021
Methylphenidate HCL Tablets	21040420	20	5/25/2021
Methylphenidate HCL Tablets	21040421	20	5/24/2021
Methylphenidate HCL Tablets	21040422	20	5/27/2021
Methylphenidate HCL Tablets	21060663	20	7/13/2021
Methylphenidate HCL Tablets	21060664	20	7/6/2021
Methylphenidate HCL Tablets	21060665	20	7/6/2021
Methylphenidate HCL Tablets	21070868	20	8/24/2021
Methylphenidate HCL Tablets	21070869	20	8/30/2021
Methylphenidate HCL Tablets	21070870	20	8/30/2021
Methylphenidate HCL Tablets	21091120	20	10/18/2021
Methylphenidate HCL Tablets	21091121	20	12/7/2021
Methylphenidate HCL Tablets	21091122	20	10/18/2021
Methylphenidate HCL Tablets	21121541	20	1/3/2022
Methylphenidate HCL Tablets	21121542	20	12/28/2021
Methylphenidate HCL Tablets	21121543	20	12/28/2021
Methylphenidate HCL Tablets	22010182	20	3/10/2022
Methylphenidate HCL Tablets	22010183	20	3/21/2022
Methylphenidate HCL Tablets	22010184	20	3/18/2022
Methylphenidate HCL Tablets	22030477	20	4/28/2022
Methylphenidate HCL Tablets	22030478	20	4/28/2022
Methylphenidate HCL Tablets	22030479	20	4/18/2022

Comment No. 2, concerning Ascent Attachment 7:

Ascent has provided two competing versions of a DEA Form 222, Order No. 200324373, for oxycodone/APAP 10/325 mg 500-ct bottles. In August 2022, Ascent gave to DEA a version in which Part 3 was handwritten. In November 2022, Ascent gave to DEA a version in which Part 3 was typed. Some inconsistencies are noted below. See attachment for reference.

1. **August version:** item #18 stated 2,000 packages were ordered, and that on April 19, 2022, 1,944 packages were shipped. **November version:** item #18 stated 2,000 packages were ordered, and that on May 23, 2022, 1,956 packages were shipped.

2. **August version:** item #19 stated 2000 packages were ordered, and that on April 19, 2022, 1,968 packages were shipped. **November version:** item #19 stated 2000 packages were ordered, and that on April 19, 2022, 1,944 packages were shipped.
3. **August version:** item #20 stated 2000 packages were ordered, and there is no indication anything was shipped. **November version:** item #20 stated 2000 packages were ordered, and that on April 19, 2022, 1,968 packages were shipped.

Please provide any secondary shipping records in Ascent's possession relating to DEA Form 222 Order No. 200324373 that show which version, if either, is accurate.

Please also provide an explanation for why Ascent would have two different (and inconsistent) versions of a single DEA Form 222.

Response to Comment No. 2:

Today Ascent has sent to your office its secondary shipping records relating to DEA Form 222 Order No. 200324373. Those records include:

- 1) Shipping documents (Packing Slip along with Vault log sheet) for the DEA Form 222, Order No. 200324373 for Oxycodone/APAP 10/325 mg, 500-ct bottles for line items 18, 19 and 20 ([Attachment-2A](#))
- 2) ARCOS report document submitted in May 2022 for DEA Form 222, Order No. 200324373 for Oxycodone/APAP 10/325 mg, 500-ct bottles for line items 18 and 19, shipped on April 19, 2022. ([Attachment-2B](#))
- 3) ARCOS Report document submitted in June for DEA Form 222, Order No. 200324373 for Oxycodone / APAP 10/ 325 mg, 500-ct bottles for line item 20, shipped on May 23, 2022 ([Attachment-2C](#))
- 4) The complete handwritten copy of DEA 222 form ([Attachment-2D](#))

Those records reflect that the handwritten form is accurate.

Ascent has two versions of the form because of its past record keeping process, that includes an original handwritten form and a typed electronic copy. It did so for operational convenience. That process is as follows:

- Ascent receives DEA Form 222 from the purchasing entity.
- Ascent makes an electronic copy of the form and keeps it accessible to Controlled Drug Substance (CDS) personnel, including associates.
- When the product is ready for shipping, an CDS associate enters the relevant information in electronic form using packaging and shipping documents.
- Since a DEA Form 222 may include multiple items and each item is shipped on different dates, information related to each shipment is typed when the shipment is processed. Ascent follows this practice to avoid entry errors.
- Once each shipment is processed, the CDS associate in charge enters the information in the original DEA Form 222 and keeps the electronic copy with supporting documents.

Here, there are discrepancies between the two copies because the employee who made the typed copy accidentally skipped row number 18 when entering data. As a result, the substance of the information reflected in rows 18-20 is the same, but the order is different.

- In the typed copy, Ascent made entries on April 19, 2022, but skipped the 18th row and typed on 19th and 20th rows. On May 23, 2022, Ascent used the 18th row to record another shipment.
- But in the handwritten form, Ascent recorded the entries in order of date shipped. As a result, Ascent recorded the April 19, 2022 shipments in the 18th and 19th rows and the May 23, 2022, shipment on the 20th row.

Ascent provided to the DEA in August a scanned copy of partially filled DEA Form 222, which it scanned before entering information in column number 20. When Ascent received a request in November, it inadvertently submitted the typed copy.

Ascent is committed to addressing this error. From now on:

- 1) Ascent will provide to the DEA only handwritten DEA Forms 222.
- 2) Ascent will discard any electronic DEA Forms 222 that it creates for operational purposes once all shipments are made that are reflected that particular form.
- 3) Ascent will consider its handwritten DEA Forms 222 as its official records.

Comment No. 3, concerning Ascent Attachments 11 and 12:

Ascent has not produced BMRs or BPRs for Lot #20121235 and 20121237. Kindly provide a complete set of BMRs and BPRs for these batches.

Response to Comment No. 3:

Today Ascent has sent to your office the BMRs and BPRs for Oxycodone Tablets 30 mg [Lot # 20121235 and 20121237 \(Attachment-3\)](#).

During its inspection, the DEA requested BMRs and BPRs for batches that were issued in 2021 and 2022. Since Ascent was not aware of scope of the investigation, Ascent did not provide BMRs and BPRs that were carried forward from 2020 as in process. Ascent is now providing copies of BMRs and BPRs for the following products that were carried forward from 2020 as in process, to 2021 ([Attachment-4](#)). Please find the following BMRs and BPRs for products with Lot numbers and shipped date in the following table-2

[Table-2](#)

Product Name	Lot #	Strength	Date Shipped
Oxycodone and APAP Tablets	20101017	10	1/21/2021
Oxycodone and APAP Tablets	20101018	10	1/21/2021
Oxycodone and APAP Tablets	20111068	10	1/21/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20101004	5	1/4/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20111144	5	1/4/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20111145	5	1/4/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20111146	5	1/4/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20111147	5	1/14/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20121168	5	1/14/2021
Hydrocodone Bitartrate and APAP Tablets 5/325	20121169	5	1/18/2021
Hydrocodone Bitartrate and APAP Tablets	20121211	5	1/18/2021
Hydrocodone Bitartrate and APAP Tablets	20121212	5	1/18/2021
Hydrocodone Bitartrate and APAP Tablets	20121213	5	1/18/2021

Hydrocodone Bitartrate and APAP Tablets	20121214	5	1/19/2021
Hydrocodone Bitartrate and APAP Tablets	20121215	5	2/15/2021
Hydrocodone Bitartrate and APAP Tablets	20121216	5	2/15/2021
Combined Granulation for Oxycodone HCL	20121232	15 &30	N/A
Combined Granulation for Oxycodone HCL	20121233	15 &30	N/A
Oxycodone HCL Tablets	20121234	15	1/25/2021
Oxycodone HCL Tablets	20121236	15	1/25/2021

Thank you for your attention to this matter.

Sincerely,

OBERHEIDEN P.C.
Counsel for Ascent